infection, and so forth) and its complications while having poor weight gain. On the other hand, if the infant could avoid these exposures, the data suggest that waiting might not be detrimental. As expected, CPB resulted in greater risk than procedures that did not require its use; however, the outcomes were similar for both weight groups. Our findings approximate the success rates found in previous studies.[13,14] Previous studies[2-15] have reported the single-center experience from highly specialized centers. These reports typically included only limited numbers of patients in the very-low-weight group, because this is such a unique population. In contrast, our study has provided the accumulated experience of many small and mid-size centers across the United States and Canada. Thus, the information from our study is unique and helpful as more cardiac centers consider early cardiac repair for low-weight neonates. The morbidity and long-term outcomes should be studied further as more infants in this population undergo early corrective surgery.

Cardiologists, surgeons, and neonatologists must collaborate to prepare the patient for surgery and should not use weight as the sole factor for operative timing, because these infants will have poor weight gain until the correction is performed.[18] The techniques and skill levels are continuously improving, making it ever safer to correct complex cardiac malformations. Knowing the likelihood of success can help the decision of when to operate and affords families realistic expectations of the final outcome.

CHD

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Discussion

Dr Peter J. Gruber *(Philadelphia, Pa).* Dr Shepard, thank you for your very clear presentation on this difficult set of patients and, especially, your willingness to review over 105,000 charts.

We are frequently faced with decisions as to when to operate on small infants, and, when we need to do so, we must decide on the best operative strategy, whether palliation or complete repair, as well as the timing. Certainly, in the past 10 years there has not been much hesitancy on the part of most surgeons to perform complex operations, regardless of weight, for purely technical reasons. Indeed, as you point out in your presentation, there has been substantial data reporting the safety and benefits of expeditious surgery, even in small infants. However, there is also, as you point out, considerable evidence that complications increase with lower body weight. The most prominent among these is the comprehensive analysis of the Society of Thoracic Surgeons database reported 2 years ago by Dr Curzon that compared the mortality in patients weighing less than and more than 2.5 kg for several operative procedures. The results of that study comprehensively documented an increase in mortality for the group weighing less than 2.5 kg for many operative groups.

You asked a different question using a different approach and divided that highest risk group into 2 categories, those less than 1.5 kg and those greater than 1.5 kg but less than 2.5 kg, and to my knowledge, the precise analysis of this group has not previously been reported.

To me, the results were a little surprising. One might have expected that those less than 1.5 kg would have had worse outcomes than those greater than 1.5 kg, and, in general, you showed that they did not.

So I have 3 questions for you.

The first is on the elaboration of the Pediatric Cardiac Care Consortium (PCCC) and its relationship to the Society of Thoracic Surgeons database and whether any of these patients overlap—

450 infants from almost 50 centers within 25 years is about 1 per center every 2 years, which is a highly heterogeneous group.

Dr Shepard. First, regarding the PCCC, this is a database that was started in 1982 at the University of Minnesota that through the years has grown. Programs have added themselves and other taken themselves out of this database throughout those years. There is overlap with the Society of Thoracic Surgeons database (some centers participate in both databases), and so some of these patients might have also been in that database. As to the second part of the question, we considered the participation over time for these centers. It was not as heterogeneous as 1 patient every other year per institution. There were institutions that during the 25-year period entered as few as 1 patient, and I believe the most patients from any given institution was about 11. This is such a small specialized population that it is very hard to find large numbers for this group.

Dr Gruber. The second question, I would be curious to know whether you noted historical differences in patients operated on during almost a quarter of a century. There has been considerable refinement in the techniques both intra- and perioperatively. Did you see any improvement over that time?

Dr Shepard. We know from previous studies that in heavier weight infants and children, there was an improvement in surgical outcomes over time. In our study, we evaluated by 5-year periods and found no improvement over time for this low-weight population, looking at all institutions. There might have been more of an effect if we had isolated just the larger institutions and looked at their improvement curves over time; however, that was not part of this study.

Dr Gruber. My last question is regarding gestational age. Were these patients small for gestational age and/or premature? Certainly, there is a close relationship between prematurity and small for gestational age, but they might underscore different mechanisms of risk. Can you comment?

Dr Shepard. That is a very important point, and one that I would very much like to look into further. That information was not included uniformly in our database so that would need to be a case-by-case review. However, I believe that would add more light to this subject, as would other questions of preoperative variables that added in and led to the timing of these procedures that were unclear from the data that we have in our database.

Dr Harald L. Lindberg *(Oslo, Norway).* I have no disclosures. Congratulations on a very nice paper.

But I wonder, were there any deaths in the group that was waiting for surgery? Do you have any information on that at all? Because that would be a really major influence on your results if you have a certain percentage of death or morbidity from waiting for surgery, that would advocate earlier repair.

Dr Shepard. This database records the cardiac operations and catheterizations so those patients who do not make it to surgery or cardiac catheterization will not be in the database. That would be a wonderful addition to this study if I could find that information.

Dr Lindberg. A second question, do you have any information if there were more patients on the ventilator or inotropic support in the group that waited for surgery or those who were primarily operated?

Dr Shepard. These preoperative co-factors would help us to understand why some patients were operated on early versus late and might offer further insight into the question of surgical timing in these high-risk infants. The PCCC does not record that information, so it would have to come from a chart-by-chart review, with charts from 47 different centers.

Dr Ali Dodge-Khatami *(Hamburg, Germany).* Among these patients there were a lot of shunts, coarctations, and also pulmonary artery bandings. For those of us in the room who are perhaps less bold to undertake such surgery in these very small infants, I did not get what percentage of these cases were done electively or what percentage were done because you had no other choice, with your back to the wall, let us say, extreme cyanosis or, on the other hand, cardiac failure?

The corollary to that question would be, if you do have the choice of waiting a bit longer to perhaps let the infants grow a bit more—of course, 38 more days in the hospital is a long time with cost issues, et cetera—but would it be justified to wait in some of these patients if you can? Do you have that percentage?

Dr Shepard. I do not have that percentage or that information. We did not have, again, the reason for timing of the intervention of the operation. That is something that would be very beneficial to add on as a follow-up to this study to determine why the timing was such and whether there would be an advantage to waiting or a reason for going early.

Dr Glen Van Arsdell *(Toronto, Ontario, Canada).* That was a nice presentation and you have done a nice job explaining the limitations of the paper because you did not have the ability to enroll based on an intention to treat.

One of the questions I have is how did you choose the weight for creating the 2 groups? Some studies have taken the approach of saying let us look at risk on an incremental weight basis. Did you analyze weight as a continuous variable as opposed to a categorical variable?

Dr Charles Shepard. We did not analyze weight as a continuous variable. We chose 1.5 kg as the marker that had been set in the past as a very high-risk category. Then, in an attempt to have a comparison group, we chose those that were at a heavier operative weight but similar birth weights and similar risk assessment for congenital heart surgery scores.

Dr Van Arsdell. It might be an interesting analysis to do, because a number of studies have shown that weight, as an incremental component, is a risk of poor outcomes.